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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------|------------------|
| 09/774,936  | 01/31/2001  | Bradley A. Ozenberger | AHP 98126 1C1       | 5327             |
| 22204   | 7590        | 10/20/2004            | EXAMINER            |                  |
| <b>NIXON PEABODY, LLP</b><br>401 9TH STREET, NW<br>SUITE 900<br>WASHINGTON, DC 20004-2128 |             |                       |                     | GUCKER, STEPHEN  |
| ART UNIT  |             | PAPER NUMBER          |                     |                  |
|   |             | 1647                  |                     |                  |

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/774,936             | OZENBERGER ET AL.   |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Stephen Gucker         | 1647                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 02 January 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 and 16-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/29/01.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## RESPONSE TO AMENDMENT

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. Claims 1-2, 4-7, 10, 16-18, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "degenerate variant" is recited in these independent claims or claims which depend from them. However, "degenerate variant" does not appear in, nor is it defined in the specification. There appears to be no conception of a "degenerate variant" *per se*, using those words, in the specification as originally filed, as recited in the instant claims. Therefore, "degenerate variants" is not adequately described by the specification in order to meet the written description requirement.
4. Claims 2, 6-7, 10, 16-18, and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims reciting biological deposits still fail to meet all

of the requirements for biological deposits. A suggested format for such a declaration or averment is outlined below:

**SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL**

A declaration by applicant, assignee or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that ensure that access to the material will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 AND 35 USC122.
6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.
7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.
8. That he/she declares that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section1001 of Title 18 of the Unites States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

The particular omissions in Applicant's declaration filed 7/15/04 concerning deposits under the Budapest Treaty are underlined in the suggested declaration format set forth above.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (Accession) number, name and address of the depositor, and the complete taxonomic description.

As a possible means of completing the record, Applicant may submit a copy of the deposit receipt.

Claims 28-30 are not enabled because the specification does not provide adequate guidance or any working examples of a non-functional BPP derived by means of amino acid modification of residues 123-202 of SEQ ID NO:2. The critical amino acid residues that bestow upon the BPP its biological function are not identified, and as the previous Office Action argued by way of the Rudinger reference, it is unpredictable how a function of a protein will be modified when its amino acid structure is changed, and such determinations must be made by undue experimentation by modifying one, some, or all of the amino acids of the encoded sequence in order to bestow upon the protein its desired and recited biological properties without a reasonable expectation of success, and any single or set of modifications would not necessarily be predictive of other modifications that would meet the limitations of the instant claims.

5. Claims 10, 16-18, and 31-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide, nucleic acid, or host cell comprising SEQ ID NO:1 or nucleic acids capable of hybridizing under

specified and recited conditions to the complement of SEQ ID NO:1 that encode a  $\beta$ -amyloid peptide-binding protein (BBP), does not reasonably provide enablement for polynucleotides that encode a  $\beta$ -amyloid peptide-binding protein (BBP) or nucleic acids capable of hybridizing to SEQ ID NO:1 or its complement by reference to the hybridization conditions of Table 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record and the following. Table 1 of the instant specification (pages 9-10) does not set forth a set of completely fixed hybridization processes that limit the instant claims (which are product-by-process claims) to that which is adequately supported by the disclosure. The hybridizations temperatures needed to adequately limit the claims commensurate with the disclosure are missing from Table 1 because the temperatures are not presented as a set temperature (e.g. 42 degrees, etc.) but as a variable temperature to be determined by the G/C content of every single one of the hybridizing species of nucleic acids encompassed by the broad claims. It is not possible to predict in advance from the encoding nucleotide sequences which encoded protein will have the biological property of amyloid binding and which will not because of the inherent uncertainty in the art of predicting protein function from structure. In effect, if a BBP encoding nucleic acid was discovered that had no similarity at all with the instant invention (SEQ ID NO:1) and was not envisioned by the instant invention, by merely knowing the G/C content of this novel BBP encoding sequence, a hybridization temperature could be selected using the criteria of Table 1 (see page 10) that would encompass totally unrelated (to SEQ ID

NO:1) nucleotide sequences because the hybridization temperature could be selected so that it would be low enough to include sequences that had little sequence identity to SEQ ID NO:1 as long as said sequences encoded a protein that had the desired biological property of amyloid binding. Because such unrelated sequences (sequences that share little sequence identity with SEQ ID NO:1 but do encode a protein that binds amyloid) are not envisioned, described, or disclosed in the specification, it would require undue experimentation with no reasonable chance of success for the skilled artisan to make the genus of claimed hybridizing sequences to the full, reasonable scope of the claims. For instance, it would be possible by using a very low hybridization temperature to allow an encoding sequence to an antibody or Fab fragment that binds  $\beta$ -amyloid to hybridize to SEQ ID NO:1, meeting the limitations of the claims, even though the instant disclosure has nothing to do with nucleotide sequences encoding antibodies that bind  $\beta$ -amyloid. Therefore, Applicants could theoretically choose a hybridization temperature to encompass any nucleic acid that had the requisite properties of encoding a BBP, regardless of its similarity to SEQ ID NO:1.

6. Claims 10 and 16-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and the following. The metes and bounds are indefinite because Table 1 of the instant specification (pages 9-10) does not set forth a set of adequately fixed hybridization processes that define the instant claims (which are product-by-process claims) to that which can be readily recognized by the public as the protected invention. The hybridizations temperatures

needed to adequately define the claim boundaries are missing from Table 1 because the temperatures are not presented as a set temperature (e.g. 42 degrees, etc.) but as a variable temperature to be determined by the G/C content of every single one of the hybridizing species of nucleic acids encompassed by the theoretically broad claims. Dependent upon the specific temperature selected, the metes and bounds of the claim will vary. Because the specific temperature is not selected "in advance" and set forth clearly in the claim language, the claims are vague and indefinite as the product so claimed can only be defined by the specific conditions of the processes that produce said product.

The instant claims also recite the "complement" of a nucleic acid sequence. It is presumed that Applicant intended to mean "full complement" as "the complement" can be interpreted as meaning a single or a couple of complementary nucleotides, and not the complete, full-length complementary sequence. The grounds of this portion of the rejection could be obviated by amending "the complement" to "the full complement".

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 31-35 are rejected under 35 U.S.C. 102(a) as being anticipated by Bonaldo et al. ("Bonaldo"). Bonaldo teaches a 523 bp sequence that shares 99.8% sequence identity along its entire length with instant SEQ ID NO:1 (see attached

sequence comparison) which would hybridize to SEQ ID NO:1 under even the most highly stringent conditions due to Bonaldo's sequence possessing only a single nucleotide mismatch along its entire length with SEQ ID NO:1.

**9.** Claims 10, 16-21, 24, 28-30, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonaldo. These instant claims are not being afforded the effective filing date of 60/064,583, filed 4/16/97, because this provisional application does not identify, teach, or claim the specific regions or fragments of SEQ ID NO:1 as does the instant application (i.e. these instant claims would be rejected for new matter if they were presented in the provisional application). Bonaldo teaches a 523 bp sequence that shares 99.8% sequence identity along its entire length with instant SEQ ID NO:1 (see attached sequence comparison) which would hybridize to SEQ ID NO:1 under even the most highly stringent conditions due to Bonaldo's sequence possessing only a single nucleotide mismatch along its entire length with SEQ ID NO:1.

In regards to claims 28-30, the Bonaldo sequence meets the negative limitations of the claims in regards to encoding amino acids 123-202 of SEQ ID NO:2 with one or more amino acid residue modifications resulting in its functional modification.

**10.** Claims 8, 9, 11, and 12 are in condition for allowance.

**11.** As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

October 4, 2004

Brenda Brumback  
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